

REMARKS

Claims 42, 43, 45, 46, 51, 56, 65-68, 76, and 84-124 are pending. Due to a Restriction Requirement, claims 51, 56, 65-68, and 76 are withdrawn from consideration. Claims 42, 43, 45, 46 and 84-124 are examined. Claim 124 is allowed. Claims 42, 43, 45, and 84-88, 110-114, and 116-120 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and further, as failing to comply with the enablement requirement. Claims 42, 43, 45, 46, and 84-123, are rejected 35 U.S.C. § 112, second paragraph. Claims 42, 43, 45, 84-88, and 110-113 are rejected under 35 U.S.C. § 102(b) over International Application Publication No. WO 91/13991. Each of these rejections is addressed below.

Amendments to the claims

Claims 46, 87, 110-113, 116, and 118 have been cancelled. Claims 42, 43, 45, 84-86, 88-91, 94, 99, 100, 106-109, 114, 115, 117, and 119 have been amended. Claims 125-131 have been added. All page and line numbers below reference the English language specification filed in the above-captioned application on July 27, 1998.

Claim 42 has been amended to recite an oligonucleotide consisting of one concatenation coding for a polypeptide of formula $(P-K)_n$, where n is 3, 4, 5, 6, 7, 8, 9, 10, or 15. Support for this change may be found at page 5, lines 10-12. Claim 42 has also

been amended to recite at least one lysine at the 5' end or the 3' end of the concatenation, or both. Support for this change is found, for example, at page 6, lines 8-12.

Claim 43 has been amended to recite an oligonucleotide consisting of one concatenation coding for a polypeptide of formula (P-K)_n, where n is 4, 6, 7, 8, 9, 10, or 15. Support for this change is found, for example, at page 5, lines 10-12. Claim 43 has also been amended to recite one or more codons at the 5' or 3' end of the concatenation. Support for this change is found, for example, at page 6, lines 8-12, and in original claim 4. Claim 43 has further been amended to recite "allows for expression of the modified γ -zein protein in a plant cell and allows for similar or identical localization of said modified γ -zein protein as compared to the unmodified protein in a plant cell." Support for these changes is found, for example, in original claim 26.

Claim 45 has been amended to depend from and to correspond with the language of amended claim 43.

Support for the changes to claims 84 and 85 is as detailed above for claims 42 and 43. Claims 84 and 85 have further been amended to recite "wherein said concatenation is interrupted once between two (P-K) units by amino acids that are neither P nor K." Support for this change is found, for example, at page 5, lines 24-27. Claim 86 has been amended to recite "wherein said bonds are peptide bonds." Support for this change is found, for example, in original claim 1 and at page 5, line 3. Claim 88 has been amended to recite "said interruption comprises at least one lysine codon at the 3' end of said

interruption.” Support for this change may be found in the sequence K-(P-K)₄-E-F-K-(P-K)₄ (SEQ ID NO:24) on page 20, line 17. Claim 89 has been rewritten into independent form and recites SEQ ID NOS:21, 23, and 24. Support for these sequences is found, for example, at page 20, lines 15-17.

Claim 90 has been amended to recite the language of claims 42 and 84, and to specify γ -zein, in accordance with the claim preamble. Claim 91 has been amended to correspond with the language of amended claim 90. Claim 94 has been amended to replace “for example” with “or.” Claims 99, 100, 106, and 107 have been amended to correspond with the language of amended claim 90. Claim 108 has been amended for clarity. Claims 109, 114, 115, and 119 have been amended to specify γ -zein. Support for this change is found, for example, original claim 41 and at page 12, line lines 4-5. Claim 114 has also been amended similarly to claim 90. Claim 117 has been amended to recite “said bonds are peptide bonds.” Support for this change is found, for example, in original claim 1 and at page 5, line 3.

Support for new claims 125 is found, for example, in the H45 γ Z sequence in Figure 3 and page 20, line 17. Claim 126 recites the language of claim 90, with the addition of “and one or more codons at the 5’ or the 3’ end of said concatenation.” Claim 127 recites “wherein said one or more codons comprise at least one lysine residue at the 5’ end or the 3’ end of said concatenation.” Support for the changes in claims 126 and 127 is found, for example, at page 6, lines 8-12 and in original claim 4. Claim 129, 130,

and 131 recites a plant producing the polypeptide encoded by the polynucleotide of claim 90 or claim 126, a method of producing such a plant, and seed including a modified γ -zein, thereby reciting language of claims 108, 109, and 114, respectively.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

Claims 42, 43, 45, and 84-88, 110-114, and 116-120 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 87, 110-113, 116, and 118 have been cancelled, thus rendering the rejection as applied to these claims moot. The Office rejects the claims on the grounds that the claims do not specify an upper limit for the length of the P-K units or for the length of non P-K units. The claims are also rejected on the grounds that they recite any plant reserve protein. Each of these rejections is address below.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (M.P.E.P. § 2163(II)). As outlined below, applicants

have provided a representative number of species of each claimed genus and have therefore met their burden under the written description requirement.

The rejection on the grounds of failing to not specify an upper limit or the length of P-K units has been rendered moot by the claim amendments. In particular, claims 42, 43, 84, 85, and 114 have been amended to recite specific numbers of P-K units no larger than 15 and now recite “consisting of” language. Claim 42 has also been amended to recite an uninterrupted single concatenation. The written description rejection on these grounds, as applied to claims 42, 43, 84, 85, and 114 and their dependent claims, should be withdrawn.

The rejection on the grounds of failing to specific an upper limit to the length of non P-K intervening regions has also been rendered moot by the amendments to the claims. Claim 42, as noted above, has been amended and does not include an intervening region. Claims 43 and 85, which have been rewritten into independent form, and claim 84 and its dependent claims, have been amended to recite a functional limitation of “wherein the polypeptide coded for by said oligonucleotide, when incorporated into a γ -zein protein at an allowable site, allows for expression of the modified γ -zein protein in a plant cell and allows for similar or identical localization of said modified γ -zein protein as compared to the unmodified protein in a plant cell.” Thus, the number of additional codons that can be included in the claimed oligonucleotides cannot prevent normal expression or localization of a modified γ -zein protein including the sequence coded for

by the claimed oligonucleotides of claims 43, 84, and 85 and their dependent claims. The written description rejection on this ground, as applied to these claims, should also be withdrawn.

With regard to the written description rejection on the grounds of encompassing any plant reserve, applicants have amended claim 114 and its dependent claims to recite a γ -zein protein. The exemplary lysine-enriched γ -zein proteins and recitation of the particular oligonucleotide sequences which may be inserted into such γ -zein proteins both describe a substantial portion of the claimed genus and provide structural and functional features of the claimed sequences. In view of these amendments, applicants believe that these claims meet the written description requirement. The rejection of claims 114 and its dependent claims should therefore be withdrawn.

New claims 129, 130, and 131 recite plants and seeds expressing γ -zein. With regard to the written description requirement of the new claims, applicants draw the Office's attention to examples in the specification. Expression of modified γ -zein is described in the present specification in *Arabidopsis thaliana* (page 34) and wheat (page 38). Applicants submit that such disclosure is sufficient to describe γ -zein expression, generally, in plants and seeds. Thus, these claims likewise comply with the written description requirement.

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

Claims 42, 43, 45, 84-88, 110-114, and 116-120 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. For the following reasons, and in view of the amendments to the claims described above, this rejection is respectfully traversed.

To fulfill the enablement requirement, a claim must be supported by a disclosure that contains sufficient information regarding the claimed subject matter to enable one skilled in the pertinent art to make and use the claimed invention (M.P.E.P. § 2164). Further, experimentation required to practice the claimed invention must not be undue.

The Office has included claims 42, 43, 45, and 84-88, in the enablement rejections; however, the enablement rejection in Office action is directed to modified plant reserve proteins and plants transformed with such proteins. No basis for an enablement rejection of the claimed oligonucleotides is provided, and applicants believe that the rejection of these claims under 35 U.S.C. § 112, first paragraph, for failure to comply with the enablement requirement should be withdrawn. As noted above, claims 42, 43, 84, and 85 have been amended to specify the number of (P-K) units in a concatenation and to provide function limitations of the claimed oligonucleotides. On this basis as well, applicants submit that the enablement rejection of claims 42, 43, 84, 85 and their dependent claims should be withdrawn.

With regard to the enablement rejection as applied to plant protein reserves of claim 114 and its dependent claims, applicant note that the maize seeds of claim 114 have been amended to recite γ -zein. Applicants submit that these claims, as amended, comply with the enablement requirement. The Federal Circuit has held that a disclosure of exemplary embodiments of a claimed invention and a method for producing the claimed subject matter is sufficient to enable a claim to a broader genus has been held to meet the enablement requirement. In *Johns Hopkins University v. Cellpro, Inc.* (152 F.3d 1242, 47 U.S.P.Q.2d 1705 (Fed. Cir. 1998)), the court held that a single method for making a CD34 antibody and a single exemplary antibody is sufficient to enable a claim to the genus of CD34 antibodies. In the present application, by providing several working examples and methods that one of ordinary skill could use to identify new oligonucleotides and modified proteins encompassed by the claimed invention, applicants submit that they have more than met their burden under the enablement requirement. The enablement rejection as applied to claims 114 and its dependent claims, should therefore be withdrawn.

New claims 129, 130, and 131 recite plants and seeds expressing γ -zein. With regard to enablement of the new claims, applicants draw the Office's attention to examples of modified γ -zein expressed in *Arabidopsis thaliana* (page 34) and wheat (page 38). Further, applicants have shown expression of lysine rich zeins in the leaf of *Arabidopsis* (see Alvarez et al., *Planta* 205:205-207, 1998; cited by the Examiner in the

Office action mailed December 10, 2004). In view of this evidence, applicants submit that the examples in the specification and knowledge in the art is sufficient to enable one of ordinary skill in the art to expression γ -zein expression, generally, in plants or seeds.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 42, 43, 45, 46, and 84-123 are rejected under 35 U.S.C. § 112, second paragraph. Claims 42 and 84 are rejected as failing to set forth the metes and bounds of the invention as not setting an upper limit on the size of the recited concatenation.

Without agreeing to this rejection, applicants have amended claims 42 and 84, as well as claims 43, 85, and 90, now recite specific lengths of concatenations, thus rendering this rejection moot.

The Office rejects claim 89 as reciting the formula $K-(P-K)_4$, while depending from a claim that requires at least six (P-K) units. Claim 89 has been rewritten into independent form, thus rendering this objection moot. The rejection on these grounds should be withdrawn.

Claims 42, 84, 110, 111, and 114 and their dependent claims 43, 45, 46, 85-109, 112-113, and 115-123 are rejected for reciting “for example” and “in particular.” This language has been deleted from the claims, thereby rendering this rejection moot. The rejection on these grounds should be withdrawn.

Finally, applicants note that claims 42, 84, 109, and 130 now recite an optional element or step. A claim reciting elements “A, B, and optionally C” is not indefinite, as such language introduces no uncertainty or ambiguity as to what the claim covers (M.P.E.P. § 2173.05(h)(III)). As the noted claims recite such an optional element, applicants submit that these claims are likewise not indefinite and in an allowable form.

Rejection under 35 U.S.C. § 102(b)

The Office has rejected claims 42, 43, 45, 84-88, and 110-113 under 35 U.S.C. § 102(b) as anticipated by WO 91/13991. To anticipate a claim, a reference must teach each and every limitation of that claim. The Office asserts that this reference teaches a sequence that includes P-K-P-K-P-K-Q-E-A-M-P-K which is included in the claimed subject matter. Applicants submit that the claims, as amended, are free from the prior art.

Claim 42 has been amended to recite an oligonucleotide consisting of a sequence encoding (P-K)_n concatenation where n is 3, 4, 5, 6, 7, 8, 9, 10, or 15 and optionally at least one lysine codon at either the 5' or 3' of the concatenation. As WO 91/13991 does not teach, explicitly or inherently, or suggest such a sequence with all of these limitations, applicants believe that amended claim 42 is free from the prior art. The rejection 35 U.S.C. § 102(b), as applied to this claim, should be withdrawn.

Claim 43 has been amended to recite an oligonucleotide consisting of an uninterrupted sequence encoding a (P-K)_n, where n is 4, 6, 7, 8, 9, 10, or 15 and one or more codons at the 5' or 3' end of the concatenation, where a γ -zein protein incorporating the polypeptide coded for by the oligonucleotide at an allowable site can be expressed in a plant cell and exhibits similar or identical localization as compared to the unmodified protein in a plant cell. WO 91/13991 does not teach or suggest an oligonucleotide encoding a concatenation of 4 or more P-K units of claim 43 and thus does not teach each and every limitation of claim 43. The rejection of this claim and its dependent claims under 35 U.S.C. § 102(b) should therefore be withdrawn.

Claim 84 has been amended to recite an oligonucleotide coding for a sequence consisting of a single (P-K)_n concatenation interrupted once by residues that are neither proline nor lysine, where n is 4, 5, 6, 7, 8, 9, 10, or 15, and optionally including at least one lysine residue at the 5' or 3' end of the concatenation, where a γ -zein protein incorporating the polypeptide coded for by the oligonucleotide at an allowable site can be expressed in a plant cell and exhibits similar or identical localization as compared to the unmodified protein in a plant cell. Applicants submit that WO 91/13991, while teaching a nucleic acid sequence coding for three P-K units separated from one P-K unit by residues that are neither proline nor lysine, does not teach an oligonucleotide consisting of such a sequence, with or without at least one lysine codon at its 5' or 3' end, as recited in claim 84. Accordingly, WO 91/13991 does not teach each and every limitation of claim

84 and therefore cannot anticipate this claim. The rejection of this claim under 35 U.S.C. § 102(b) should therefore be withdrawn.

Claim 85 has been amended to recite an oligonucleotide coding for a sequence consisting of a single (P-K)_n concatenation interrupted once by residues that are neither proline nor lysine, where n is 7, 8, 9, 10, or 15, and including one or more codons the 5' or 3' end of the concatenation, where a γ -zein protein incorporating the polypeptide coded for by the oligonucleotide at an allowable site can be expressed in a plant cell and exhibits similar or identical localization as compared to the unmodified protein in a plant cell. WO 01/13991 only teaches a sequence including P-K-P-K-P-K-Q-E-A-M-P-K; thus, it does not teach a concatenation interrupted once where n is 7, 8, 9, 10, or 15, interrupted once, or any of the other limitations of claim 85. The rejection of this claim and its dependent claims under 35 U.S.C. § 102(b) should therefore be withdrawn.

Claims 110-113 have been cancelled, thereby rendering the rejection under 35 U.S.C. § 102(b) moot.

Applicants also submit that the claims as amended are free from Gaisser (GenBank Accession No. S80675), which was cited in the Office action mailed December 10, 2004.

Gaisser discloses the sequence of the tonB gene, which includes the sequence KPKPKPKPKPKVEKQVKPEPKK. This sequence can be represented as K-(P-K)₅-X-(P-K)₁K. The closed, "consisting of" language of claim 42 which recites an oligonucleotide encoding (P-K)_n concatenation where n is 3, 4, 5, 6, 7, 8, 9, 10, or 15 and

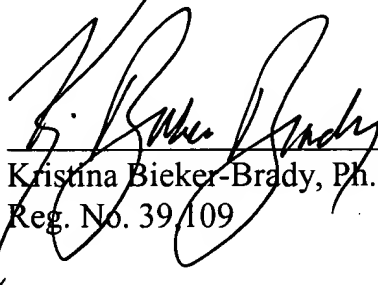
optionally at least one lysine codon at either the 5' or 3' does not include the sequence of Gaisser. Claim 43 also does not include the sequence of Gaisser, as this claim does not include a (P-K)_n concatenation where n = 5. Likewise, Gaisser does not disclose the oligonucleotide of claim 84, which recites an oligonucleotide consisting of a sequence coding for (P-K)_n, interrupted once, with optionally at least one lysine residue at its 5' or 3' end, where n is 3, 4, 5, 6, 7, 8, 9, 10, or 15. Claim 85 recites oligonucleotide consisting of a sequence coding for (P-K)_n, interrupted once, with one or more oligonucleotides at its 5' or 3' end, where n is 7, 8, 9, 10, or 15. As Gaisser only teaches a sequence (P-K)_n interrupted once where n is 6, applicants submit that this claim is free from the teachings of Gaisser.

CONCLUSION

Applicants submit the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three (3) months, to and including November 17, 2006, and a check in payment of the required extension fee. Also enclosed is a check in the amount of \$1,200.00 for five (5) additional independent claims (\$1,000.00) and four (4) additional total claims (\$200.00). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: November 17, 2006



Kristina Bieker-Brady, Ph.D.
Reg. No. 39/109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045